

**Notice of Allowability**

Application No.

10/622,055

Examiner

Zachary C. Tucker

Applicant(s)

CERNERUD ET AL.

Art Unit

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2 March 2007.
2. ☒ The allowed claim(s) is/are 1-14, 16, 18, 19, 21-33, 36, 40 and 44.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone conversation between the examiner and applicants' counsel, John T. Kendall, on 13 March 2007.

#### **IN THE CLAIMS -**

Claim 18 has been amended as follows:

18. A method for the treatment of ~~a disorder or medical condition that is associated~~ with neuroleptic drug-induced extrapyramidal symptoms, the method comprising administering to a subject in need thereof a therapeutically effective amount of a compound according to claim 1.

end of amendment

**Response to Amendment**

As requested in applicants' correspondence, filed 2 March 2007 (dated 28 February 2007; hereinafter "present amendment"), which is in reply to the Final Rejection mailed 29 August 2006 (hereinafter "previous Office action"), claims 18, 21, 24, 36, 40 and 44 have been amended, and claims 17, 20, 34, 35, 37-39 and 41-43 have been cancelled.

**Status of Claim Rejections - 35 USC § 112**

Because the methods specified therein were not supported by an enabling disclosure and were indefinite in scope, claims 17, 18 and 34-44 were finally rejected under 35 U.S.C. 112, first and second paragraphs, in the previous Office action.

The rejection of claims 17, 34, 35, 37-39 and 41-43 is now moot, because those claims have been cancelled.

The rejection of claims 36, 40 and 44 has been overcome by the present amendment; the rejections of those claims under 35 U.S.C. 112 are hereby withdrawn. Claim 36 is now limited to the treatment of *insomnia* or *sleep apnea* instead of sleep disorders in general, claim 40 is now limited to the treatment of *thrombosis* instead of thrombotic illnesses in general, and claim 44 is now limited to *nephropathy*, *neuropathy* and *retinopathy* as diabetic complications instead of diabetic complications in general.

Claim 18 is allowable by virtue of the attached Examiner's Amendment, authorized by applicants. Treatment of neuroleptic drug-induced extrapyramidal symptoms is enabled by the disclosure; treatment of "a disorder or medical condition that is associated with neuroleptic drug-induced extrapyramidal symptoms" is not.

In the previous Office action, claims 24, 25 and 27 were rejected under the second paragraph of 35 U.S.C. 112, for indefiniteness – specifically because the limitations "at an

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elevated temperature” was recited in claim 24, from which claims 25 and 27 depend. Deletion of the phrase “at an elevated temperature” has obviated the rejection; the rejection is hereby withdrawn.

#### ***Status of Claim Objections***

In the previous Office action, claims 21-23 and 26 were objected to because the structures depicted in those claims were not completely legible. In view of the present amendment to claim 21, which introduces a corrected molecular structure diagram for formula (II), the starting material in the method therein claimed, the objection is hereby withdrawn.

#### ***Erratum***

At page 15 of the previous Office action, in lines 4 and 5, the statement “Parkinson’s disease or ‘diabetic complications’ could be treated by administering a compound of the present invention to an individual in need thereof.” appears. This statement should have read “... could not be treated by administering a compound of the present invention ...” It appears that applicants understood what was actually intended.

#### ***Allowable Subject Matter***

Claims 1-14, 16, 18, 19, 21-33, 36, 40 and 44 are allowed.

Reasons for indicating allowable subject matter were provided on page 10 of the Non-Final Office action mailed 28 December 2005 and throughout the previous Office action (comments as to the allowability of the claimed methods-of-treatment).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany

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the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

All Post-Allowance Correspondence concerning this application must be mailed to:

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.



**ZACHARY C. TUCKER  
PRIMARY EXAMINER**